

Remarks/Arguments

Reconsideration of this Application and entry of this Amendment are respectfully requested. Applicant thanks Examiner Vanik for his time in the recent telephone interview and for his courteous and insightful comments regarding the pending claims in the instant application. Applicant has made the following amendments consistent with the Examiner's comments.

Claims 1, 3, 4, 6, 7 and 10-26 were pending in this application as of the mailing date of this Office Action. Claims 10-22 were previously withdrawn without prejudice as the result of an earlier restriction requirement and are canceled herein in order to present the pending claims in condition for allowance. Claims 2, 4, 5, 6, 8-22 and 26 have been canceled without prejudice to Applicant's right to pursue the subject matter of the withdrawn and canceled claims in one or more related applications.

As a result of this amendment claims 1, 3, 7, 23-25 and 27 remain pending in this application. Claim 27 has been added to further claim Applicant's invention. Support for the amount of insoluble material present in the claimed compositions in claim 27 can be found in the specification, as filed, in paragraph 0068. Therefore the elements present in new claim 27 do not represent new matter.

Applicant acknowledges that the 35 USC §101 rejection is withdrawn as a result of Applicant's amended claims filed on April 6, 2006, and the 35 USC §103 rejection over RU 2176411 in view of US Patent 3,896,238 has also been withdrawn.

Rejections under 35 U.S.C. §112

Claims 1, 3, 4, 6, 7 and 23-26 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement for containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the invention was filed, had possession of the claimed invention." June 2, 2006 Final Office Action page 5.

Applicant has amended independent claim 1 to remove the limitation "wherein said therapeutic composition is not an extract of said substantially pure powdered

Spongilla sp.” Additionally, the term Spongilla sp. was removed and the term “species *Spongilla lacustris*” was used in its stead, thereby incorporating the limitation of claim 6. Claims 4, 6 and 26 have been canceled.

Additionally, claim 23 stands rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement for containing subject matter which was not described in the specification in such a way as to reasonable convey to one skilled in the relevant art that the inventor(s), at the time the invention was filed, had possession of the claimed invention.” June 2, 2006 Final Office Action page 6.

Claim 23 has been amended to change the phrase “at least 0.1%” to “approximately 0.1% to approximately 100%.” Support for this claim amendment can be found in the specification, as originally filed, in paragraph 0042 as stated by the Examiner.

Therefore, in light of the above claim amendments, Applicant respectfully requests that the 35 U.S.C. §112, first paragraph rejections of currently pending claims 1, 3, 7 and 23-25 be withdrawn.

Rejections under 35 U.S.C. §102(a)

Claims 1, 3, 4, 7 and 24-25 stand rejected under 35 U.S.C. §102(a) as being anticipated by RU 2176511 C1 (the ‘511 reference). As stated by the Examiner, “[b]y disclosing a composition comprising a Porifera-derived product, a fresh-water sponge of the Spongillidae family, the composition advanced by ‘511 et al anticipates the instant claims 1 and 7 (abstract).” June 2, 2006 Final Office Action page 3.

Furthermore, the Examiner has submitted that language in claim 1 contains product-by-process language and that these phrases neither “breath meaning or add breadth to the instant claim set.” June 2, 2006 Final Office Action page 4.

Without acquiescing to the Examiner’s rejections, Applicant hereby amends independent claim 1 as stated below to overcome the rejection over the ‘511 reference.

1. A therapeutic composition for treating skin diseases comprising:

a substantially pure powder of a fresh water sponge of the species *Spongilla lacustris*~~substantially pure powdered *Spongilla* sp. made in accordance with Good Manufacturing Practices (GMP)~~ and at least one pharmaceutically acceptable excipient wherein said therapeutic composition ~~is not an extract of said substantially pure powdered *Spongilla* sp~~ comprises insoluble material of said substantially pure powder of *Spongilla lacustris* and wherein said insoluble material comprises skeletal spicules.

Applicant submits that amended claim 1 does not contain product-by-process language. The language regarding Good Manufacturing Practices was deleted for clarity reasons only to remove functional language and therefore Applicant does not disclaim products made by Good Manufacturing Practices.

Furthermore, Applicant has added the limitation that said therapeutic composition "comprises insoluble material of said substantially pure powder of a fresh water sponge of the species *Spongilla lacustris* and wherein said insoluble material comprises skeletal spicules." Support for the species *Spongilla lacustris* can be found in original claim 6, now canceled. Support for the term "substantially pure powder" can be found in paragraph 0085 of the specification which defines "substantially pure" as a preparation "that has been separated from environmental debris including rocks, sticks, other marine life etc., washed, dried, ground sieved and sized." Additional support for the term "substantially pure powder" can be found in paragraph 0096 of the specification. Support for the limitation "said therapeutic composition comprises insoluble material" is found in paragraph 0068 which states "approximately 50 to 60% percent remains insoluble and comprises the organic fraction providing compositions with mechanical-abrasive properties." Support for the limitation "said insoluble material comprises skeletal spicules" is found in paragraph 0062 which states "[f]urthermore, refined organic residue, such as, but not limited to skeletal spicules, mechanically separate epidermis surface layers reduces the keratinocytes cohesion thereby increasing stratum

corneum sloughing and sebum plug and loose keratinocyte removal, which opens pores and prevents future occlusion and consequent formation of comedones."

The '511 reference discloses a "water-alcohol extract of a freshwater sponge of the family Spongillidae" (page 3 of the translation provided by the Examiner in the Office Action mail 12/06/2005). The '511 referenced does not disclose any other preparation of freshwater sponges than water-alcohol extracts. Moreover, the water-alcohol extract of the '511 referenced does not contain any insoluble materials. As stated on page 5 of the translation, "[i]n order to obtain a water-alcohol sponge extract, the ground sponge is extracted with 40-70% ethyl alcohol and the suspended particles are removed."

A claim is anticipated only if each and every element as set forth in a claim is found, either expressly or inherently described, in a single prior art reference *Verdegaaal Bros. V. Union Oil Co. of California*, 814 F.2d, 628, 631, 2 USPQ2d 1051 (Fed. Cir. 1987).

Currently amended claim 1 states that the claimed invention comprises insoluble materials and that the insoluble material comprises skeletal spicules. The '511 reference does not disclose compositions containing insoluble material and furthermore does not disclose skeletal spicules.

Therefore, the '511 reference does not disclose each and every element of amended independent claim 1 and dependent claims 3, 7, 23-25 and 27 of the instant application. Claims 4 and 26 have been canceled. Applicant respectfully requests that this rejection under 35 U.S.C. §102(b) be withdrawn.

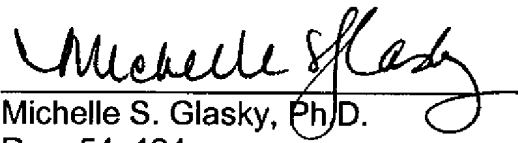
Conclusion

Claims 1, 3, 4, 6, 7, and 23-26 were pending in the instant application before the current amendment, claims 2, 4, 5, 6, 8-22 and 26 have been canceled and new claim 27 has been added. For the foregoing reasons, Applicant believes pending claims 1, 3, 7, 23-25 and 27 are in condition for allowance and should be passed to issue. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call Louis C. Cullman at 949-253-0900.

The Commissioner is authorized to charge any fee which may be required in connection with this action or credit any overpayment to deposit account No. 50-3207.

Respectfully submitted,

Dated: 6/19/06


Michelle S. Glasky, Ph.D.
Reg. 54, 124

PRESTON GATES & ELLIS LLP
1900 Main Street, Suite 600
Irvine, California 92614-7319
Telephone: 949.253-0900
Facsimile: 949.253-0902

Customer No.: 45,200